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Substitute	e for form 1449/PTO			Complete if Kn wn		
				Application Number	09/896,812	
INFO	RMATION	DIS	CLOSURE	Filing Date	June 29, 2001	
STAT	TEMENT BY	Y A	PPLICANT	First Named Inventor	Madden, Thomas D.	
• • • • • • • • • • • • • • • • • • • •				Art Unit	1615	
	(use as many she	ets as	necessary)	Examiner Name	Gollamudi S. Kishore	
Page	1	of	3	Attorney Docket Number	016303-008030US	

	U.S. PATENT DOCUMENTS						
		Document Number					
Examiner	Cite No.1	Number Kind Code ² (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Cotumns, Lines, Where Relevant Passages or Relevant Figures Appear		
LIM	. AA	US-5,023,087	06/11/1991	Yau-Young			
V/2-	AB	US-5,552,156	09/03/1996	Burke			
W	AC	US-5,837,282	11/17/1998	Fenske et al.			

				OREIGN PA	TENT DOCUM	ENTS		
Examiner Initials*	Cite No.1		Foreign Patent Docum	ent		Name of Patentee or	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T ⁶
		Country Code	Number ⁴	Kind Cade ⁶ (# known)	Publication Date Fig. 12 MM-DD-YYYY Fig. 12 MM-DD-YYYYY Fig. 12 MM-DD-YYYY Fig. 12 MM-DD-YYYY Fig. 12 MM-DD-YYYY Fig. 12 MM-DD-YYYYY Fig. 12 MM-DD-YYY	Applicant of Cited Oocument		
In	AD	PCT	WO 95/08986	A1	04/06/1995	SmithKline Beecham Corporation		
~ }	AE	PCT	WO 98/17256	A1	04/30/1998	Kirpotin, Dmitri		
	AF	PCT	WO 99/51202	A2	10/14/1999	Sequus Pharmaceuticals, Inc.		
///	AG	PCT	WO 00/23052	A1	04/27/2000	Alza Corporation		
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Page	2	of	3	Attorney Docket Number	016303-008030US	一フ	

		NON PATENT LITERATURE DOCUMENTS	
Examiner Initials *	Cite No.1	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T²
In	- AH	BURRIS III et al., "Activity of topotecan, a new topoisomerase I inhibitor, against human tumor colony-forming units in vitro," Journal of the National Cancer Institute 84(23):1816-1820 (1992)	
	· AI	CLEMENTS et al., "Antiangiogenic potential of camptothecin and topotecan," Cancer Chemother. Pharmacol. 44:411-416 (1999)	
	· AJ	EMERSON et al., "In vivo antitumor activity of two new seven-substituted water-soluble camtothecin analogues," Cancer Research 55:603-609 (1995)	
	· AK	ERICKSON-MILLER et al., "Differential toxicity of camptothecin, topotecan and 9-aminocamptothecin to human, canine, and murine myeloid progenitors (CFU-GM) in vitro," Cancer Chemother. Pharmacol. 39:487-472 (1997)	
	· AL	GROCHOW et al., "Pharmacokinetics and pharmacodymanics of topotecan in patients with advanced cancer," Drug Metabolism and Disposition 20(5):708-713 (1992)	
	AM	HARDMAN et al., "Efficacy of treatment of colon, lung and breast human carcinoma xenografts with: Doxorubicin, cisplatin, irinotecan or topotecan," Anticancer Research 19:2269-2274 (1999)	
	· AN	HSIANG et al., "Identification of mammalian DNA topoisomerase I as an intracellular target of the anticancer drug camptothecin," Cancer Research 48:1722-1726 (1988)	
	· AO	MADDEN et al., "The accumulation of drugs within large unilamellar vesicles exhibiting a proton gradient; a survey," Chemistry and Physics of Lipids 53:37-48 (1990)	
	· AP	MADDEN et al., "Encapsulation of topotecan in lipid-based carrier systems. Evaluation of drug stability and plasma elimination in a murine model, and comparison of antitumor efficacy against murine L1210 and B16 tumors," Proc. of ASCO, 17:abstract #754 (1998)	
	, AQ	MAYER et al., "Characterization of liposomal systems containing doxorubicin entrapped in response to pH gradients," Biochimica et Biophysica Acta 1025:143-151 (1990)	
	AR	McCABE et al., "Comparative activity of oral and parenteral topotecan in murine tumor models: Efficacy of oral topotecan," Cancer Investigation 12(3):308-313 (1994)	
	' AS	O'LEARY et al., "Antiangiogenic effects of camptothecin analogues 9-amino-20(S)-camptothecin, topotecan, and CPT-11 studied in the mouse comea model," Clinical Cancer Research 5:181-187 (1999)	
	- AT	ORMROD and SPENCER, "Topotecan: A review of its efficacy in small cell lung cancer," <i>Drugs</i> 58(3):533-551 (1999)	
w	, AU	TARDI et al., "Liposomal encapsulation of topotecan enhances anticancer efficacy in murine and human xenograft models," Cancer Research 60:3389-3393 (2000)	

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

Complete If Known **Application Number** 09/896,812 Filing Date June 29, 2001 Madden, Thomas D. First Named Inventor 1615 Art Unit **Examiner Name** Gollamudi S. Kishore Attorney Docket Number 016303-008030US

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Examiner Signature	Kida	Date Considered	10/5/06	

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